K002054

FEB 1 6 2001

Attachment 2
510(k) Summary (Updated)

Submitter Information	
Submitter's Name	Appriva Medical, Incorporated
Address	777 North Pastoria Avenue Sunnyvale, CA 94086
Telephone Number	(408) 616-5203
Contact Person	Michael Kolber Vice-President, Regulatory Affairs and Quality Assurance
Submission Prepared	July 5, 2000

A. Device Information

a. Proprietary Name: X-SEPT Transseptal Sheath and Transition Catheter

b. Common or Usual Name: Introducer Catheter

c. Classification Name: Introducer Catheter

d. Predicate Device:
Cook Check-Flo® Performer Introducer Set (with Radiopaque marker and Mullins Type) (K895044)
Arrow Transseptal Super Arrow-Flex® Percutaneous Sheath Introducer Set (K970229)
Cordis Webster Preface™ Guiding Sheath (K895044)

e. Device Description

The X-SEPT Transseptal Sheath and Transition Catheter is a percutaneous, transluminal, access sheath. The sheath is designed to function similarly to a standard transseptal sheath during transseptal puncture and access of the left atrium. Once the transseptal dilator and needle are withdrawn, the additional curvature enables the sheath to be positioned in the desired location. The proximal end of the catheter has a hemostatic valve.

The Transition Catheter is a simple, single lumen catheter with an atraumatic tip at its distal end, and a Luer lock at its proximal end. The function of the Transition Catheter is to provide a smooth transition from the primary diagnostic device (for instance, a pig tail diagnostic catheter or steerable electrophysiology catheter) to the Transseptal Sheath.

f. Intended Use

The Appriva Medical, Inc. X-SEPT Transseptal Sheath and Transition Catheter is indicated for percutaneous introduction of various cardiovascular devices into the left side of the heart through the atrial septum.

B. Summary of Technological Characteristics of Current Device Compared to the Predicate Device

The technical characteristics of the device are substantially equivalent to the predicate devices, including product design, packaging, sterilization, and labeling.

C. Support of Substantial Equivalence

The device is substantially equivalent to the following legally marketed product: 1) Cook Check-Flo Performer Introducer Set (with Radiopaque marker and Mullins Type) (K89044), 2) Arrow Transseptal Super Arrow-Flex® Percutaneous Sheath Introducer Set (K970229) and 3)
Cordis Webster Preface™ Guiding Sheath (K895044).

In-vitro and biocompatibility tests were performed to demonstrate that the Appriva Medical X-SEPT Transseptal Sheath and Transition Catheter is as safe, as effective and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 6 2001

Mr. Michael Kolber
Vice President, Regulatory Affairs and Quality Assurance
Appriva Medical, Incorporated
777 North Pastoria Drive
Sunnyvale, CA 94086

Re: K002054
Trade Name: X-SEPT Transseptal Sheath and Transition Catheter
Regulatory Class: II (two)
Product Code: DYB
Dated: November 29, 2000
Received: November 30, 2000

Dear Mr. Kolber:

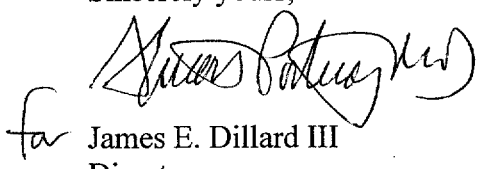
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002054

Device Name: X-SEPT Transseptal Sheath and Transition Catheter

Indications For Use:

The MV Medical Devices, Inc. X-SEPT Transseptal Sheath and Transition Catheter is indicated for percutaneous introduction of various cardiovascular devices into the left side of the heart through the atrial septum.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

9-15-1

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K002054

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)